# *LIFE SCIENCES AND MEDICAL TECHNOLOGIES:* CROs, CMOs AND CSOs

Duane Morris®

**ENABLING SOLUTIONS.** ***Advising leading life sciences contract organizations on providing health insights and solutions.***

Duane Morris offers up-to-date advice on contracting, compliance and regulatory developments and solutions that facilitates seamless integration of contract services for translating cutting-edge concepts and discoveries to the market.

We provide both small and large CROs, CSOs, CDMOs and CMOs valuable services that help them drive the development of drugs, devices, biologics and other products and services in life sciences and healthcare. Whether it is assisting companies that engage in early discovery of new products, advising companies that develop and manufacture products (both clinical and preclinical) or providing services to companies that perform clinical trials, our lawyers provide valuable counsel to those companies that are integral to the product life cycle in the life sciences and medical device industry. Employing a multidisciplinary approach to this industry is essential and part of Duane Morris' collaborative mission. We draw upon our deep experience in life sciences and medical devices, licensing and contracting, healthcare, intellectual property (such as patent and trade secret litigation and patent and trademark prosecution), FDA and other regulatory services, real estate and leasing, finance, corporate acquisitions and structuring, products liability counseling, as well as the experience of other groups to provide the background necessary to assist in our clients' success.

With offices throughout the United States, Europe and Asia, Duane Morris is well positioned to assist its clients worldwide. The following are examples of where we can help:

### Contract Research Organizations and Contract Science Organizations

> Representing CROs and CSOs or companies contracting with them in clinical trial arrangements, patient data transfers, data management and regulatory advice.

> Representing CROs or companies contracting with them in all research and development agreements, drawing on our knowledge of intellectual property, contracting, regulatory affairs, healthcare, privacy, HIPAA and security.

> Providing advice when CROs and CSOs are navigating the complexities of prosecuting, protecting and exploiting valuable intellectual property in addition to transferring intellectual property to customers.

> Working collaboratively across disciplines, we provide advice in all phases of your organization and are attentive to often ignored business issues.

### Contract Manufacturing and Development

> Representing large and small companies at the forefront of contract manufacturing and development in all aspects of their business.

> Advise clients on drafting and negotiating manufacturing, supply, development and quality agreements advising on intellectual property issues, providing guidance on regulatory issues such as FDA 483 letters or other FDA or Department of Justice investigations.

> Meaningful advice and representation in product liability and related matters including in structuring effective responses to warranty claims, recalls and product liability litigation.

## RANGE OF SERVICES

- Contract Negotiation
- Regulatory Audits and Responses
- Product Liability Claims
- Recall Strategies
- IP Licensing/Diligence
- Clinical Trials
- Patent Prosecution
- HIPAA and Privacy
- IP Strategy/Prosecution
- IP Litigation
- Corporate Formation
- Debt and Equity Financings
- Merges and Acquisitions
- Stakeholder Disputes
- Collaborations/Partnering
- Commercial Contracts
- Corporate Governance
- Commercial Litigation
- White-Collar/Government Regulatory
- Employment and Labor
- Benefits
- Immigration Services and Compliance
- Import/Export Regulatory Compliance
- Non-Compete & Trade Secrets

## RANKINGS

- Ranked by Juristat as a TOP 3 LAW FIRM for Patent Prosecution in Biotechnology and Organic Chemistry
- Ranked by Legal 500: United States 2025 as a LEADING LAW FIRM in Life Sciences
- Ranked by LMG Life Sciences 2024 among leaders in Patent Prosecution

## REPRESENTATIVE MATTERS

- Represented IQVIA INC. (NYSE: IQV), a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry, in connection with its acquisition of all shares of capital stock of Cronos Clinical Consulting Services Inc., a leading global provider of specialty clinical service solutions with the goal of improving data quality in clinical trials.
- Co-lead counsel for CATALENT, a leading contract development and manufacturing organization, in patent infringement litigation concerning a treatment for epilepsy. After defeating the plaintiff's motion for a preliminary injunction, the plaintiff voluntarily dismissed its case with prejudice.
- Represented OLOGY BIOSERVICES INC., a Florida-based developer and manufacturer of drugs and biologics with government contracts awarded, in its sale to life sciences startup National Resilience; the acquisition provides Resilience with 300 skilled employees as well as more than 200,000 square feet of manufacturing, office, process development, quality assurance and quality control space across locations in Florida, California and Maryland.
- Represented EMILY'S ENTOURAGE, a nonprofit organization focused on rare mutations of cystic fibrosis, in their partnership with a leading clinical trial organization.
- Represented PIRAMAL GROUP in its acquisition of a drug manufacturing and development facility in Pennsylvania.
- Represented a clinical stage biopharmaceutical company in the negotiation of clinical trial agreements with multiple research and educational institutions.
- Represented a canine biotechnology company in a contract dispute regarding implementation of clinical trials. Obtained a settlement the client found favorable.
- Represented PROTAGEN PROTEIN SERVICES GMBH, a world-leading German CRO and protein science expert, in its acquisition of BioAnalytix Inc., a pharmaceutically oriented American biotech company spun-out from the Barnett Institute of Chemical and Biological Analysis at Northeastern University; the transaction establishes a new method of protein analysis in the United States.
- Obtained favorable resolutions on behalf of pharmaceutical packaging manufacturer in multiple lawsuits filed by industrial machine suppliers.
- Represented CATALENT, INC. (NYSE: CTLT), the leading global provider of advanced pharmaceutical delivery technologies, in its $44.5 million purchase of the U.S. manufacturing facility of Erytech Pharma, a clinical-stage biopharmaceutical company developing innovative therapies by encapsulating therapeutic drug substances inside red blood cells.
- Represented a biopharmaceutical manufacturer in its acquisition of an existing 165,000-plus square-foot nanotechnology research and development/laboratory building and adjacent 49,000-plus square-foot expansion building under construction in Florida, together with an additional three fully developed and leased light manufacturing facilities and nine parcels of vacant land.
- Represented CATALENT, INC. (NYSE: CTLT), the leading global provider of advanced pharmaceutical delivery technologies, development and manufacturing solutions with market cap in excess of $17 billion, in its $80 million "carve-out" acquisition of the manufacturing and packaging operations of Acorda Therapeutics, Inc. (Nasdaq: ACOR), a neurological disorder therapy manufacturer and developer in Massachusetts, operating best-in-class spray drying capacity; the acquisition complemented Catalent's status as a premier U.S.-based partner for companies across dry powder inhaled dose forms.
- Represented CATALENT BIOLOGICS' (NYSE: CTLT) Paragon Gene Therapy unit, the leading viral vector development and manufacturing partner for gene therapies, in its acquisition of manufacturing equipment and related assets from, and strategic partnership with, Novavax Inc. (Nasdaq: NVAX), a late-stage biotech company developing next-generation vaccines for infectious diseases; the transaction expands Paragon's gene therapy business and offers Novavax a cost-effective solution to its manufacturing needs.
- Represented CATALENT, INC. (NYSE: CTLT), a drug delivery technology company, in its $140 million all cash acquisition via tender offer of Juniper Pharmaceuticals, Inc. (Nasdaq: JNPR), including its U.K.-based Juniper Pharma Services division.
- Represented OLOGY BIOSERVICES INC. in the closing of a sale-leaseback transaction with Senior Housing Properties Trust (SHP), whereby Ology Bioservices sold its newly constructed advanced development and manufacturing biosafety level 3 capable facility in Alachua, Florida, to SHP for $45 million and entered into a 15-year lease of such facility.
- Represented OLOGY BIOSERVICES INC. in a license amendment with Takeda, which expanded Takeda's commercialization and technology access rights related to Ology's Vero cell technology platform – a cell culture-based platform for vaccine production which Ology Bioservices acquired from Baxalta, formerly Baxter International's BioScience division.
- Represented OLOGY BIOSERVICES INC. in the purchase from Baxalta, formerly Baxter International's BioScience division, of its proprietary Vero cell technology and related assets, including its production facility in Bohumil, Czech Republic.

## FOR MORE INFORMATION, PLEASE CONTACT:


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